JUN 2 1 2001

K010874

Section 5 Summary of Safety and Effectiveness

(Pursuant To Section 12 of the SAFE MEDICAL DEVICES ACT of 1990)

5.1 General Provisions

Submitter's Name and Address	Boston Scientific / Scimed One Scimed Place Maple Grove, Minnesota 55311
Contact Person	Todd Kornmann (763) 694-5857
Classification Name	Similar to Diagnostic Intravascular Catheters (21CFR Part 970.1200)
Common or Usual Name	Coronary Guide Catheter
Proprietary Name	Boston Scientific / Scimed, 6F Mach1 Guide Catheter

5.2 Name of Predicate Devices

Boston Scientific / Scimed, 6F Wiseguide™ and Guider™Softip® Guide Catheters and Medtronic® Zuma2™ Guide Catheter.

5.3 Device Description

The shaft of the 6F Mach1 guide catheter utilizes common biocompatible materials and consists of the following three layers: 1) the inner polytetrafluoroethylene (PTFE) layer that provides a low coefficient of friction and facilitates easy passage of medical devices such as balloon dilatation catheters, guide wires or other therapeutic devices, 2) the middle layer which is made of a double braided tungsten / stainless steel wire that extends from the shaft to the tip to provide kink resistance, torque control and back-up support and 3) the outer layer, manufactured from Arnitel® (polyether-ester) which provides stiffness and memory.

The outer primary catheter shaft is constructed of multiple segments of Arnitel. These segments are composed of various durometers of Arnitel providing a distal curve area of the catheter with transitional flexibility. The catheter is assembled as components over a core mandrel. The catheter shaft is then heat fused, forming a composite catheter shaft. This process results in a continuous inner and middle layer and a seamless outer shaft layer.

The distal tip is made of Hytrel® and is radiopaque to allow visualization under fluoroscopy during a procedure.

The catheters will utilize a one piece Arnitel hub/strain relief that is molded to the proximal end of the guide catheter shaft. The 6F Mach1 Guide Catheters have a 0.070" ID. The benefit of the larger lumen size will improve dye flow through the catheter. The catheters will be available in lengths from 40 to 125 cm, with optional side holes. The devices will be provided sterile and are intended for one procedure use only.

5.4 Intended Use

The Scimed guide catheters are designed to provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

5.5 Summary of Technological Characteristics

The 6F Mach1 Guide Catheters are manufactured in a similar manner to Scimed's legally marketed 6F Wiseguide Guide Catheters (K981788) with the exception that the materials being utilized are different.

The manufacturing process and design are substantially equivalent to the Wiseguide but the materials being utilized are more representative or substantially equivalent to those being used in Scimed's legally marketed Guider Softip (K961999). Because of this both catheters will be considered predicate devices. However, because the 6F Wiseguide is the most recent device to receive 510(k) clearance it was chosen to be the representative predicate device. All of the comparison testing completed, except two tests were conducted using the 6F Wiseguide. The Guider Softip was chosen as the comparison device for the tip tensile and radiopacity tests because the materials used more closely represent the subject device.

5.6 Non-clinical Test Summary

Functional testing consisted of shaft and distal segment tensile, tip tensile, tip deflection, hub to shaft tensile, pressure shaft burst and hub leak, torque response, lumen integrity and radiopacity. Biocompatibility, packaging and product shelf life testing has also been conducted. Test results verified that the 6F Mach1 catheter is adequate for its intended use. The 6F Mach1 guide catheters are considered substantially equivalent to guide catheters legally marketed by Scimed and Medtronic based on a comparison of intended use, the design and the results of *in-vitro* testing and evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 1 2001

Mr. Todd Kornmann
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
One Scimed Place
Maple Grove, MN 55311

Re: K010874
6F Mach 1 Guide Catheter, Model 3456-XXX
Regulation Number: 870.1250
Regulatory Class: II
Product Code: DQY
Dated: March 22, 2001
Received: March 23, 2001

Dear Mr. Kornmann:

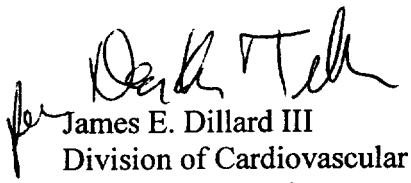
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3 — Indications For Use

510(k) Number (if known) K010874

Device Name: Boston Scientific Scimed® 6F Mach1 Guide Catheter

Indications for Use:

Scimed guide catheters are intended for use in general intravascular and coronary applications. They provide a pathway through which medical instruments, such as balloon dilatation catheters, guide wires or other therapeutic devices may be introduced. These devices are not intended for use in the cerebral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use_____
(Per 21 CFR 901.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010874